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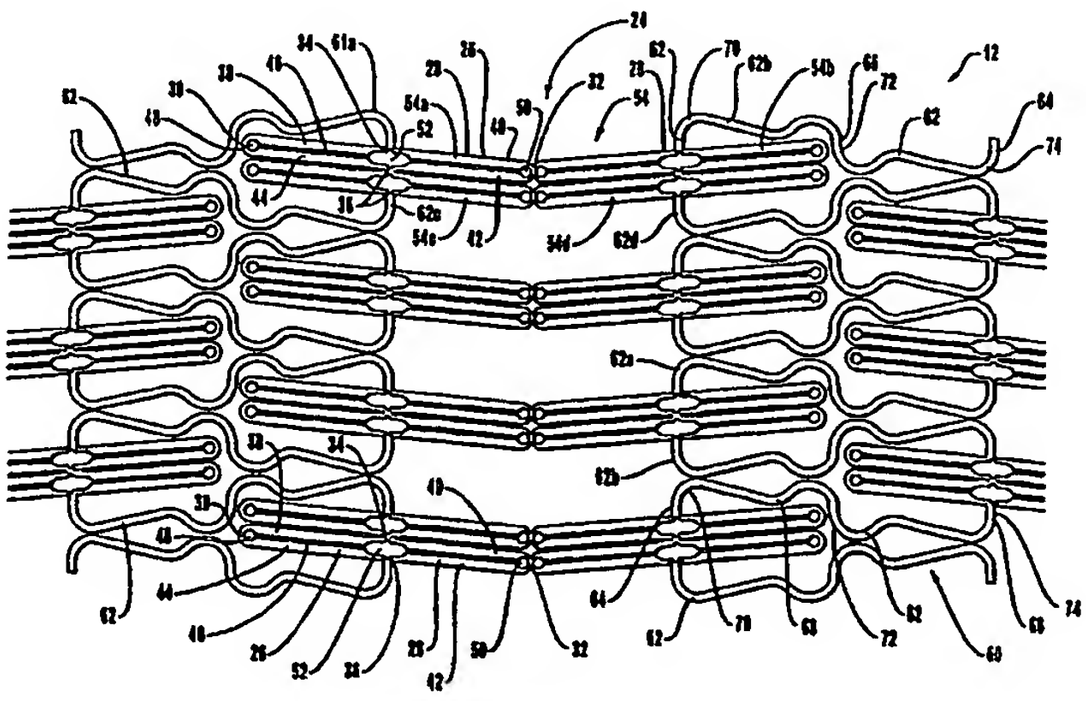

(57) Abstract: The present invention is directed towards a plurality of related embodiments, each comprising a flexible and expandable stent for insertion or implantation into a body lumen such as an artery or blood vessel. A representation illustrative version of the stent has a smaller diameter in a first nonexpanded position to allow movement of the stent within the vessel and a larger diameter in a section expanded position to hold the vessel in the original or expanded position and includes an elongated body with a plurality of radially expandable elements that are connected by, for examples, a plurality of flexible links. In one embodiment only the radially expandable elements have a generally rectangular configuration in the firs non-expanded position and a generally diamond-shaped configuration in the second expanded position. The flexible links included three curved sections that are sized and configured to straighten such that the longitudinal length of the elongated body is generally the same in the first position and in the second position. Likewise, a method of delivery and alternate embodiments are taught whereby ameliorative endovascular intervention in an affected body lumen are shown for systems wherein such treatment in indicated, or other wise may enhance survival, further tissue insult or morbidity.

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NOVEL ENHANCED FLEXIBLE EXPANDABLE STENTS

Field of the Invention

The present invention generally relates to medical devices and, in particular, to tissue supporting methods and devices such as expandable stents for insertion, implantation or emplacement into a body lumen. Likewise, those having a modicum of skill in the endovascular arts shall understand that, as defined within the instant specification, expandable comprises any known means for increasing subject devices from a first to at least a second size, position or orientation.

Description of Related Art

Stents are devices that are used during a medical variety of procedures. In particular, expandable stents are conventionally used, for example, during medical and related procedures to widen a lumen, such as a blood vessel, and to maintain the vessel in a widened or patent position. This type of stent, often referred to as an intravascular stent, initially has a relatively small diameter for inserting and maneuvering the stent within the blood vessel and an expanded diameter for applying a radially outwardly extending force against the vessel wall to hold the peripheral portion of the lumen in a widened position. The stent may be useful, for example, in the treatment of atherosclerotic stenosis and after dilation of blood vessel by balloon catheter angioplasty (e.g., percutaneous Transluminal coronary angioplasty). Artisans further are well aware that the devices and teachings of the present invention are applicable to any body lumen needing supplemental support, patency maintenance or having related indications for treatment.

Conventional stents are generally tubular in shape and, in the expanded position, the hollow center portion allows blood to flow through the stent when used to enhance vascular systems, for example. If the stent deforms or collapses from its expanded position, that obstructs or blocks the flow of blood through the vessel. Thus, the stent must have sufficient radial strength to prevent deformation or collapsing of the tubular body. In particular, the stent must resist the radially inward force of the blood vessel wall that naturally occurs when the vessel is subjected to the radial outward force of the stent. Conventional stents, however, may not have the required radial strength necessary to hold the lumen in the expanded position and if the stent collapses or deforms, that may result in serious health consequences.

Conventional stents that have sufficient radial strength to prevent deformation, or collapsing of the tubular body, on the other hand, are often difficult to use because they are not sufficiently flexible to allow the stent to be easily inserted and moved within the patient's body. Specifically, it is often difficult to maneuver the relatively ridge body of a conventional stent through the curved and often tortuous blood vessel passageways. Thus, conventional stents are commonly awkward to use and troublesome to properly position in the blood vessel because of the rigid body.

Attention is called to the following U.S. Letters Patents and foreign publications, each of which has been examined and found to be distinct from the instant teachings:

5,922,021	5,954,744	5,935,506	5,938,682
5,938,697	5,951,586	5,935,135	5,919,225
5,925,061	5,948,018	5,941,249	5,925,075
5,935,161			

A conventional stent, for example, is disclosed in U.S. Letters Patent No. 5,102,417 issued to Palmaz, et al. The Palmaz patent discloses an expandable intraluminal vascular graft including thin-walled tubular members with a plurality of slots disposed substantially parallel to a longitudinal axis of the tubular members. Because the tubular members are relatively rigid, flexible connectors are needed so that the subject stent can bend when being inserted through a curved lumen such as a blood vessel. Disadvantageously, the stent decreases longitudinally in length when it expands radially and it does not apply a generally uniform force on the inner surface of the blood vessel. This popular stent service to highlight several longstanding needs identified, addressed and overcome by the instant teachings.

Another conventional stent is disclosed in U.S. Letters Patent No. 5,104,404 issued to Wolff. The Wolff patent discloses an articulated stent with a number of individual stent segments that are flexibly connected together by hinges that are welded between adjacent stent segments. The hinges permit articulation between adjacent segments to allow the stent to be placed in an artery or blood vessel that bends. The hinges, however, must be angularly orientated such that the hinges are located on the outside portion of the bend. Thus, if the vessel curves in only one

direction, all of the hinges are located on one side of the stent. One the other hand, if the vessel curves first in one direction and then in the opposite direction, a first hinge is located on one side of the stent and a second hinge is located on the opposite side of the stent to provide the required matching stent articulation. Disadvantageously, the artery size and shape must be measured first to determine the size of the individual segments and the placing of the hinges, and then a new stent must be constructed according to the particular size and shape of the artery. Additionally, when the stent is expanded in a curved portion of the blood vessel, it does not provide a uniform force on the inner wall surface of the vessel and this creates undesirable stresses and strains on the blood vessel. Once again, distinct from the teachings of the present invention which have focused upon such issues.

Yet another conventional stent is disclosed in U.S. Letters Patent No. 5,733,303 issued to Israel, et al. The Israel patent discloses a stent for implanting in a body and the stent is formed from a tube with a series of interconnected patterns. The stent, as claimed, included a first meander pattern and a second meander pattern with axes extending in orthogonal directions. The first meander pattern is formed into even and odd patterns that are 180 out of phase with each other and each odd pattern is positioned between every two even patterns. The second meander pattern is intertwined with the first meander pattern and the second meander pattern is also formed of even and odd patterns. Each meander pattern also includes a pair of loops that open in opposite directions. Thus, the stent disclosed in the Israel patent requires first and second interrelated meander patterns with odd and even portions and pairs of oppositely opening loops. These patterns are complex and they increase the cost and difficulty in manufacturing the stent, as opposed to the instant teachings, which can be created en masse with Lasers and the like means.

Conventional stents are typically delivered and implanted into a patient's body by using known medical devices such as intravascular, or endovascular, catheters. For example, conventional stents may be mounted on an expandable member such as a balloon located near the distal end of the Intravascular catheter. The catheter and stent are then placed in the desired location in the patient's body and the balloon is inflated to expand the stent into the expanded position. The balloon is then deflated and the catheter is removed from the patient's body while the expanded stent remains in the desired portion of the blood vessel. Stents that are expanded by balloons, however, do not always uniformly expand and the outer

surfaces of the stent are not always cylindrical. As a result, healing of the blood vessel may not occur in a consistent manner and blood flowing through the vessel may be obstructed. Additionally, if the stent has a coating or covering, non-uniform expansion of the stent may tear or damage the coating. Further, if the stent has an extended length, the balloon must also have an extended length and extended length balloon catheters are difficult to handle and position in the desired portion of the blood vessel. It is noted that the present inventors have likewise patented a plurality of novel enhanced balloons and systems including U.S. Letters Patent No. 5,968,068 issued October 19, 1999, and U.S. Letters Patent No. 6,013,092, U.S.S.N. 09/135,736 for FOLDING OF CATHETER MOUNTED BALLOONS TO FACILITATE NON-ROTATIONAL RADIAL EXPANSION OF INTRALUMINAL DEVICES expressly incorporated herein by reference.

A longstanding need therefore exists for a flexible and expandable stent that eliminates the above-described disadvantages and problems, in addition to other unrequited needs in the art.

One aspect of the present invention is a flexible and expandable stent for insertion or implantation into a body lumen such as an artery or blood vessel. The stent includes an elongated body that extends along a longitudinal axis. The stent has a smaller diameter in a first nonexpanded position and a larger diameter in a second expanded position. The first position has a diameter smaller than the inside diameter of the blood vessel to allow the stent to be moved within the vessel. The second position has a diameter about the same or greater than the inside diameter of the vessel to hold the vessel in an original or expanded position.

Another aspect of the present invention is a stent that has a high degree of flexibility along its longitudinal axis in the first nonexpanded position so that it can readily advance through lumens with curved and bent sections. This flexibility allows the stent to be easily located in the desired portion of the lumen. The stent is also flexible along its longitudinal axis in the second expanded position so that the stent can be placed in arcuate portions of a lumen. In addition to being flexible, the stent has sufficient radial or circumferential strength in the second expanded position to hold the lumen in the enlarged position and the stent will not unintentionally deform or collapse.

A further aspect of the present invention is a stent that expands in a radial direction with minimal change in its overall longitudinal length. Thus, the stent does not foreshorten or decrease in length when it changes from the nonexpanded position to the expanded position. Significantly, this makes the stent easier to use because the length is generally constant. Alternatively, the stent may be configured to increase or decrease in length as it changes from the nonexpanded to expanded position.

Still another aspect of the present invention is a stent that provides a generally uniform radially outwardly extending force on the inside wall of the lumen. This generally uniform force helps prevent tearing and other injuries to the lumen wall. Additionally, as the stent expands, it provides a generally constant force on the inside wall of the lumen to prevent the lumen from being distorted or damaged. Significantly, if the stent has a coating or covering, this generally uniform expansion helps prevent the coating or covering from cracking or breaking.

Yet another aspect of the present invention is a stent constructed from a biocompatible material such as metal. The metal is preferably a shape memory metal that, after being deformed, returns to its desired shape and configuration upon being reheated to a predetermined temperature. In particular, the stent is preferably constructed from Nitinol, a shape memory metal consisting of a nonmagnetic alloy of nickel and titanium. The stent also preferably includes a coating or covering constructed of a biocompatible material such as polytetrafluoroethylene (PTFE). This covering can be embedded with materials such as medicine and the covering may be textured to help in placement and/or grafting of the stent.

Another aspect of the present invention is a stent constructed from a tubular member that is cut or etched to have the desired configuration and dimensions. In particular, the stent may be manufactured using a laser lathe and a series of mandrels with different diameters. Alternatively, the stent may be manufactured using chemical etching or other known manufacturing processes. Further, the stent may be annealed and/or heat treated such that it has a desired characteristics.

Still another aspect of the present invention is a stent that readily changes from the first nonexpanded position to the second expanded position. The stent preferably changes from the nonexpanded position to the expanded position because of a change in temperature. For example, the stent can be inserted into the body in a the nonexpanded position and at a relatively low temperature. The stent can then be

heated by the body and that causes the stent to self-expand into the second expanded position. The stent can also change from the first nonexpanded position to second expanded position by using conventional medci8al devices such as balloon catheters.

Yet a still further aspect of the present invention is an endovascular stent comprising a plurality of linked supporting members defining a tubular supporting means for maintaining patency of a body lumen, wherein at least one of one and two distinct geometrics defines the non-fore-shortening means. A preferred embodiment is a tissue supporting device including an elongated body with a generally tubular configuration that extends generally along a longitudinal axis. The elongated body includes a first nonexpanded position with a first diameter and a second expanded position with a second diameter, the second diameter being larger than the first diameter. The elongated body also includes at least one first section with one or more radially expandable elements and at least one second section with one or more flexible links. The radially expandable elements have a generally rectangular configuration in the first nonexpanded position and the radially expandable elements are sized and configured to expand radially to change the diameter of the elongated body from the first diameter to the second diameter. The elongated body preferably has generally the same longitudinal length in the first position and in the second position.

Desirably, the radially expandable elements in the first position are generally aligned with the longitudinal axis of the elongated body and the radially expandable elements in the second position have a generally diamond-shaped configuration. The radially expandable elements may also include a first hinge pint, a second hinge point, a first end and a second end which are interconnected by connecting members. Preferably, the elongated body expands from a first nonexpanded position to a second expanded position when the body is hearted to a predetermined temperature, such as the temperature of the tissue to be supported. More preferably, the elongated body is constructed from a shape memory metal such as an alloy containing Nitinol. Further, a coating may cover at least a substantial portion of the elongated body.

Another preferred embodiment is an expandable stent that includes an elongated body extending generally along a longitudinal axis. The elongated body includes a plurality of first sections including one or more radially expandable elements, each of the expandable elements includes four hinge points that are connected by four connecting members. The elongated body also includes a

plurality of flexible links that connect the plurality of first sections and the flexible links included one or more curved sections that are configured to straighten as the expandable stent expands from a first position to a second position. Preferably, the four connecting members are generally arranged in a parallel alignment in the first position and the four connecting members form a substantially diamond-shaped configuration in the second position. Further, the longitudinal length of the elongated body is preferably generally the same in the first position and the second position.

Yet another preferred embodiment is an expandable stent including a first nonexpanded position with a first diameter and a second expanded position with a second diameter. The expandable stent also includes a plurality of radially expandable elements and each radially expandable element includes a first connecting member being generally aligned with the longitudinal axis in the first position; a second connecting member connecting to the first connecting member, the second connecting member being generally aligned with the longitudinal axis in the first position; a third connecting member connected to the second connecting member, the third connecting member being generally aligned with the longitudinal axis in the first position; and the fourth connecting member connecting to the third connecting member, the fourth connecting member being generally aligned with the longitudinal axis in the first position. Additionally, the expandable stent includes a plurality of flexible links interconnecting the; plurality of radially expandable elements, each of the flexible links including a first end, a second end and at least one curved section. Preferably, the first, second, third and fourth connecting members form a generally rectangular-shaped configuration in the first nonexpanded position and a generally diamond-shaped configuration in the second expanded position.

Still another preferred embodiment is an expandable stent including a generally tubular body with a first nonexpanded position and a second expanded position. The expandable stent also includes a plurality of first sections, each of the first sections including one or more radially expandable elements, each of the radially expandable elements including a first end, a second end, a first hinge point positioned between the first end and the second, end, and a second hinge point positioned between the first end and the second end; and a plurality of second sections interconnecting the plurality of first sections, the second sections including

one or more flexible links having a first end, a second end, and at least one curved section. The flexible links are connected to the first or second hinge points of the radially expandable members.

A further embodiment is an expandable stent with a generally tubular configuration that extends generally along a longitudinal axis. The stent includes a plurality of first sections and each first section includes a plurality of radially expandable elements having a first end, a second end, a first hinge point and a second hinge point. The racially expandable elements also include a first connecting member connecting the first end and the first hinge point, a second connecting member connecting the first hinge point and the second end, a third connecting member connecting the second end and the second hinge point, and a forth connecting member connecting the second hinge point and the first end. The stent also includes a plurality of second sections interconnecting the first sections to form the generally tubular body. Each second section includes a; plurality of flexible links and each flexible link includes at least one curved section.

A still further embodiment is a stent for expanding a lumen in a body. The stent includes one or more first portions with a plurality of radially expandable elements, each of the radially expandable elements having a plurality of connecting members that are connected at a plurality of hinge points and the radially expandable elements are sized and adapted to expand into a generally diamond-shaped configuration. The stent also includes one or more second portions connected to each of the first portions. Each of the second portions include a pair of flexible links with a first end with a first curved section, a second end with a second curved section and a center portion with a third curved portion. Preferable, the first curved section and the second curved portion are curved at an angle greater than 90 and the flexible links in each pair of flexible links are mirror images or each other.

Further aspects, features and advantages of the present invention will become more fully apparent from the following detailed description of the preferred embodiments and the appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

The appended drawings contain figures of preferred embodiments of the expandable stent. The above-mentioned aspects, features and advantages of the

expandable stent, as well as other aspects, features and advantages, will be described in connection with the preferred embodiments. Understanding that these preferred embodiments are only intended to illustrate the invention and not limit its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Figure 1 is a perspective view of a flexible, expandable stent in accordance with a preferred embodiment of the present invention;

Figure 2 is a plan view of a portion of the stent shown in Figure 1, illustrating the expandable stent in a flattened or generally planar configuration;

Figure 3 is an enlarged plan view of a portion of the stent shown in Figure 2, illustrating a radially expandable element sand the flexible links;

Figure 4 is a plan view of a portion of flexible, expandable stent in accordance with another preferred embodiment of the present invention, illustrating the expandable stent in a flattened or generally planar configuration;

Figure 5 is an enlarged plan view of a portion of the stent shown in Figure 4, illustrating the radially expandable elements and the flexible links;

Figure 7 is a plan view of the stent shown in Figure 5, illustrating the stent in a radially expanded position;

Figure 8 is an elevational view of a stent embodying features of the present invention mounted on a delivery catheter and disposed within an artery, illustrating a portion of the delivery catheter and disposed within an artery, illustrating a portion of the delivery catheter and a sheath covering the stent;

Figure 9 is an elevational view of a stent shown in Figure 8, illustration the stent in an expanded position within the artery, with the delivery catheter partially cut-away and the sheath withdrawn;

Figure 10 is an elevational view of the stent shown in Figure 9, illustrating the stent expanded within the artery and the delivery catheter withdrawn;

Figure 11 is an elevational view of a stent embodying features of the present invention mounted on an expandable element of a delivery catheter and disposed within an artery, illustrating a portion of the delivery catheter and a sheath covering the stent;

Figure 12 is an elevational view of a stent shown in Figure 11, illuminating the stent in an expanded position within the artery, with the delivery catheter partially cut away and the sheath withdrawn;

Figure 13 is an elevational view of the stent shown in Figure 12, illustrating the stent expanded within; the artery and the delivery catheter withdrawn;

Figure 14 is a schematized view of an alternate embodiment of a stent according to the present invention;

Figure 15 is a schematized view of an alternate embodiment of a stent according to the present invention;

Figure 16 is a schematized view of an alternate embodiment of a stent according to the present invention;

Figure 17 is a schematized view of an alternate embodiment of a stent according to the present invention; and

Figure 18 is a schematized view of an alternate embodiment of a stent according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present inventors have discovered that it is possible to create stents having non-foreshortening means incorporated in their respective geometries which overcome longstanding endovascular issues.

The present invention involves and expandable stent. The principles of the present invention, however, are not limited to expandable stents. It will be understood that, in light of the present disclosure, the stents disclosed herein can be successfully used in connection with various types of tissue supporting devices and other tubular members.

Additionally, to assist in the description of the expandable stent, words such as right, left, upper, lower, longitudinal and radial are used for simplicity in describing the accompanying figures. It will be appreciated, however, that the present invention can be located in a variety of desired positions—including various angles, sideways and even upside down. A detailed description of a representative embodiment of a typical expandable stent now follows. It is understood that this description applies to each disclosed iteration.

As seen in Figure1, a preferred embodiment of the present invention includes an expandable stent 10 with an elongated tubular body 12 that extends along a longitudinal axis 14. The longitudinal axis 14 is centrally located within the tubular body 12 and radially outwardly extending from the longitudinal axis is a radial axis 16. The body 12 also includes a first end 18, a second end 20 and a central portion

22 located between the ends. The body 12 preferable has a generally circular configuration with a generally constant diameter, but the body can also be tapered, conical, stepped, etc. depending upon the intended use of the stent 10.

As best seen in Figure 2, which illustrates a flattened portion of the stent 10, and Figure 3, which illustrates an enlarged portion of Figure 2, the body 12 includes a series of first sections 24 that are generally radially aligned about the circumference of the stent 10 and spaced apart along the longitudinal length of the stent. Each first section 24 includes one or more radially expandable elements 26 that are configured to expand radially to increase the diameter of the stent 10. The radially expandable elements 26 shown in Figures 1-5 are not radially expanded but, as described below, the radially expandable elements 26 shown in Figures 6 and 7 are radially expanded.

As best seen in Figure 3, the radially expandable elements 26 preferably consist of flexible cells 28 which, in the nonexpanded position, are generally aligned with the longitudinal axis 14 of the body 12. In greater detail, each radially expandable element 26 has an elongated body with a first end 30 and a second end 32 that are generally longitudinally aligned with the longitudinal axis 14. A first hinge point 34 and a second hinge point 36 are positioned between the first end 30 and the second end 32 of the stent 10. The hinge points 34 and 36 are preferably centrally located proximate the midpoint between the ends 30 and 32, respectively, but the hinge points may be positioned in any desired location between the ends. In greater detail, a first connecting member 38 connects the first end 30 with the first hinge point 34, a second connecting member 40 connects the first hinge point 34 with the second end 32, a third connecting member 42 connects the second end 32 with the second hinge point 36, and a fourth connecting member 44 connects the second hinge point 36 with the first end 30. The connecting members 38-44 preferably have approximately the same length such that the radially expandable elements 26 have an elongated, generally rectangular configuration in the nonexpanded position.

An opening 46 is located between the connecting members 38, 40, 42 and 44. As shown in Figures 1-3, in the nonexpanded position, the opening 46 is elongated and generally aligned with the longitudinal axis 14. The opening 46 includes an enlarged first end 48 proximate the first end 30 and an enlarged second end 50 positioned proximate the second end 32. The opening 46 also includes an

enlarged central portion 52 located near the first and second hinge points 34 and 36, respectively. The openings 46-52 preferably have generally curved surfaces to reduce stress concentrations, but the openings may have any desired shape to promote expansion of the radially expandable element 26. As discussed below, the opening 46 with the enlarged ends 48, 50 and enlarged central portion 52 facilitates radial expansion of the radially expandable elements 26.

As best seen in Figure 3, the radially expandable elements 26 preferably consist of flexible cells 28 which, in the nonexpanded position, are generally aligned with the longitudinal axis 14 of the body 12. In greater detail, each radially expandable element 26 has an elongated body with a first end 30 and a second end 32 that are generally longitudinally aligned with the longitudinal axis 14. A first hinge point 34 and a second hinge point 36 are positioned between the first end 30 and the second end 32 of the stent 10. The hinge points 34 and 36 are preferably centrally located proximate the midpoint between the ends 30 and 32, respectively, but the hinge points may be positioned in any desired location between the ends. In greater detail, a first connecting member 38 connects the first end 30 with the first hinge point 34, a second connecting member 40 connects the first hinge point 34 with the second end 32, a third connecting member 42 connects the second end 32 with the second hinge point 36, and a fourth connecting member 44 connects the second hinge point 36 with the first end 30. The connecting members 38-44 preferably have approximately the same length such that the radially expandable elements 26 have an elongated, generally rectangular configuration in the nonexpanded position.

An opening 46 is located between the connecting members 38, 40, 42 and 44. As shown in Figures 1-3, in the nonexpanded position, the opening 46 is elongated and generally aligned with the longitudinal axis 14. The opening 46 includes an enlarged first end 48 proximate the first end 30 and an enlarged second end 50 positioned proximate the second end 32. The opening 46 also includes an enlarged central portion 52 located near the first and second hinge points 34 and 36, respectively. The openings 46-52 preferably have generally curved surfaces to reduce stress concentrations, but the openings may have any desired shape to promote expansion of the radially expandable element 26. As discussed below, the opening 46 with the enlarged ends 48, 50 and enlarged central portion 52 facilitates radial expansion of the radially expandable elements 26.

One or more of the radially expandable elements 26 are grouped together to form the first sections 24. In the preferred embodiment shown in Figures 2 and 3, four radially expandable elements 26 are connected to form each first section 24, In particular, each first section 24 includes a first radially expandable element 54a, a second radially expandable element 54b, a third radially expandable element 54c and a fourth radially expandable elements. The four radially expandable elements 54a-54d are pivotally connected to form the first section 24. In greater detail, the second end 32 of the first radially expandable element 54a is preferably pivotally connected to the first end 30 of the second radially expandable element 54b, and the second end 32 of the third radially expandable element 54c is pivotally connected to the first end 30 of the fourth radially expandable element 54d. Additionally, the second hinge point 36 of the first radially expandable element 54a is pivotally connected to the first hinge point 34 of the third radially expandable element 54c, and the second hinge point 36 of the second radially expandable element 54b is pivotally connected to the first hinge point 34 of the fourth radially expandable element 54d. Thus, the four radially expandable elements 54a-54d are interconnected to form the first section 24.

Alternatively, in another preferred embodiment shown in Figures 4 and 5, the first section 24 includes six elongated radially expandable elements 56a-56f which are pivotally connected. One skilled in the art will understand that the first section 24 may include any suitable number of radially expandable elements 26 depending, for example, about the size of intended use of the stent 10. Further, it will be appreciated that the first section 24 may include only a single radially expandable element 26 and each first section does not require the same number of radially expandable elements.

As shown in Figures 1-3, the first sections 24 are generally radially aligned about the circumference of the body 12. In particular, the first sections 24 are radially space apart a generally equal distance about the circumference of the body 12 and the first sections are generally longitudinally aligned along the length of the body. Preferably, the first sections 24 are offset or staggered along the longitudinal length of the stent 10 to increase the radial strength of the stent 10. More preferably, the first sections 24 are alternated or spaced about 180 out of phase relative to the longitudinal axis 14 so that longitudinally adjacent first sections are not longitudinally aligned, but every other first section is longitudinally aligned. One

skilled in the art will appreciate that the longitudinal and radial placement of the first sections 24 may vary, however, according to the number of radially expandable elements 26 in each first section 24, the diameter of the stent 10, the desired circumferential or hoop strength of the stent, and the like parameters.

The radially expandable elements 26 shown in Figures 1-5 are illustrated in a first nonexpanded position with the first connecting member 38, second connecting member 40, third connecting member 42 and fourth connecting member 44 in generally aligned and parallel positions. As shown in Figures 6 and 7, in the second expanded position, the radially expandable elements 26 are radially expanded to increase the diameter of the body 12 and the radially expanded elements form a generally diamond-shaped pattern. In particular, the first, second, third and fourth connecting members 38-44 bend or pivot about the first and second ends 30, 32 and first and second hinge points 34, 36 respectively. This causes the distance between the first hinge point 34 and the second hinge point 36 to increase and the distance between the first end 30 and the second end 32 to decrease.

The diamond-shaped pattern of the radially expandable elements 26 advantageously maximizes the radial expansion of the stent 10 and provides a large expansion ratio. The expansion ratio is the ratio of the radially expanded second position to the nonexpanded first position. Additionally, the diamond-shaped pattern provides relatively large hoop or radial strength to the body 12 and this helps prevent the stent 10 from collapsing or deforming. Further, the diamond configuration provides a strong and relatively rigid stent 10 that is generally crush resistant in the expanded position. While the radially expandable elements 26 preferably form the diamond-shaped pattern, it will be appreciated that the expandable elements can have any desired shapes such as rectangular, square, triangular, or other suitable polygon shapes.

The configuration and arrangement of the radially expandable elements 26 may be changed or modified to alter the amount of force required to expand the radially expandable elements from the first nonexpanded position to the second expanded position. Advantageously this allows the amount of force required to expand the body 12 of the stent 10 from the first position to the second position to be adjusted. For example, the size of the first and second enlarged openings 48, 50 proximate the ends 30, 32 of the radially expandable elements 26 may be increased or decreased. The size of the elongated opening 46 and/or the thickness of the

connecting members 38-44 may also be increased or decreased. Additionally, the radially expandable elements 26 may be positioned at an angle relative to the longitudinal axis 14 and the length of the connecting members 38-44 may be increased or decreased. Further, the=number of radially expandable elements 26 in the first sections 24 may be increased or decreased, and the radially expandable elements may be interconnected by means such as welding, gluing, hinges, glue, rivets, fasteners, and the like to change the amount of force required to radially expand the expandable elements.

The body 12 of the stent 10 also includes second sections 60 which interconnect the first sections 24. The second sections 60 include a series of interconnecting members of flexible links 62 that are disposed between the first sections 24. The flexible links 62 have a first end 64, a second end 66 and one or more arcuate, bent or curved sections 68. As seen in Figures 1-5, in this preferred embodiment, the flexible link 62 includes a first curved section 70 that is bent at an angle greater than 90 and positioned proximate the first end 64 of the link; a second curved section 72 that is positioned between the first and second ends 64, 66 and has a generally S-shaped configuration; and a third curved section 74 that is bent at an angle greater than 90 and positioned proximate the second end 66 of the link.

The flexible links 62 are configured to straighten as the radially expandable elements 26 radially expand and decrease in longitudinal length as the body 12 expands from the first position to the second position. Preferably, the flexible links 62 expand such that the overall longitudinal length of the stent 10 is approximately the same in the first position and the second position. Thus, there is generally no foreshortening or change in length of the stent 10 as it expands or contracts between the first and second positions. Alternatively, the flexible links 62 and radially expandable members 26 may be configured such that the overall length of the stent 10 decreases or increases as the stent changes from the first nonexpanded position to the second expanded position. The time and rate at which the flexible links 62 straighten may be controlled, for example, by the thickness, mass, amount of curvature, number of curved sections 68, and related parameters.

The flexible links 62 of the second section 60 are joined or coupled to the radially expandable members 26 of the first section 24. In particular, as shown in Figure 3, a first pair of flexible links 62a and 62c are attached to radially expandable elements 54a and 54c of a group of radially expandable elements 26 and a second

pair of flexible links 62b and 62d are attached to radially expandable elements 54b and 54d. Preferably the flexible links 62a, 62c and 62b, 62d are mirror images of each other and the flexible links are attached to the first and second hinge points 34, 36 respectively of the radially expandable elements 26. In particular, the flexible link 62a is connected to the first hinge point 34 of the radially expandable element 54a, the flexible link 62b is connected to the first hinge point 34 of the radially expandable element 54b, the flexible link 62c is connected to the second hinge point 36 of the radially expandable element 54c, and the flexible link 62d is connected to the second hinge point 36 of the radially expandable element 54d. The flexible links 62 may also be connected to other portions of the radially expandable elements 26, such as the first and second ends 30 and 32, but that results in it being more difficult to maintain a generally constant overall length of the stent 10.

The flexible links 62 interconnecting the first sections 24 provide increased longitudinal flexibility to the body 12 and that allows the stent 10 to be easily inserted through curved, often tortuous, pathways of a lumen. It will be appreciated that generally the greater the longitudinal flexibility of the stent 10, the easier and more safely it can be delivered to the implantation site. The flexible links 62 also allow the stent 10 to be expanded into the second position in a curved portion of the lumen and the expanded stent can support the lumen in the curved position. Advantageously, the flexible links 62 allow the lumen to be supported with a generally uniform radially outwardly extending force and this minimizes alteration of the natural physiology of the lumen and stress on the lumen. Further, the stent 10 expands in a generally uniform manner and it exerts a generally uniform force on the lumen, which minimizes the stress and strain on the lumen.

In a preferred embodiment for implantation into an artery of a patient, the body 12 of the stent 10, in the first nonexpanded position, has a diameter in the range of about 0.04 inches (1.0 mm) to about 0.14 inches (3.5 mm) and the stent has a diameter in the range of about 0.14 inches (3.5 mm) to about 0.50 inches (12.5 mm) in the expended position. It will be appreciated that the stent 10 may have any desired size, but the stent preferably has a smaller diameter in the first nonexpanded position than the inside diameter of the lumen to allow the stent to be moved within the lumen and, in the second expanded position, the stent preferably has a diameter generally the same or slightly larger than the inside diameter of the lumen. The stent 10 is preferably carefully sized to not tear or damage the lumen when expanding or

while maintaining the lumen in the open position. The stent 10, however, may have different sizes depending upon the particular lumen to be supported and the stent may be configured to apply different amounts of pressure or force on the inside wall of the lumen.

The body 12 of the stent 10 is constructed of a biocompatible material such as metal. For example, the body 12 may be constructed of stainless steel, gold, silver, copper, aluminum, zinc, titanium, platinum, iridium or other desired type of metal. The body 12 can also be constructed of various alloys with suitable characteristics and these alloys may be doped with small amounts of other elements for various property modifications as known to one skilled in the art. Alternatively, the body 12 could be constructed of various synthetic materials such as thermoplastic polymers or other types of plastics. Preferably, the body 12 is constructed of a shape memory metal that, after being deformed, returns to its original shape upon being reheated to a predetermined temperature. More preferably, the body 12 is constructed of nitinol, a shape memory metal consisting of a nonmagnetic alloy of nickel and titanium. The shape memory metal allows the stent 10 to be constructed in its second expanded position and then compressed or deformed into the first nonexpanded position. Advantageously, the stent 10 self-expands from the first nonexpanded position to the second expanded position simply by heating the shape memory metal to a predetermined temperature. Desirably, the predetermined temperature is approximately body temperature such that the stent 10 self-expands within the patient's body when body temperature is reached.

In another preferred embodiment, the outer portion of body 12 of the stent 10 includes a coating 80 consisting of a biocompatible material. This coasting is not shown, and those skilled in the art understand how and when the use of the same is indicated. The coating 80 is preferably polytetrafluoroethylene (PTFE) because it is insoluble in all know solvents, the coefficient of friction is extremely low and it has generally constant mechanical properties, but other suitable materials may be used. The coating 80 helps protect the stent 10 from damage and it aids in grafting the stent 10 to the lumen. The coating 80 can also be embedded with other substances such as medicine and textured to help in placement of the stent. Likewise, "ePTFE" or expanded polytetrafluoroethylene is known by those skilled in the art to be coextensive with the above described coating as described in U.S. Letters Patents No.'s 5,976,192; 5,928,279; 5,843,173; 5,641,373; and 5,071,609 each of which is

owned by the present assignee and expressly incorporated herein by reference.

As best seen in Figures 1, 2, 4 and 5, the first and second distal ends 18, 20 of the stent 10 include a radially aligned series of radially expandable elements 82 and 84, respectively. The radially expandable elements 82 and 84 are positioned about the circumference of the stent 10 and have a structure and arrangement similar to the radially expandable elements 26 discussed above. In particular, the radially expandable elements 82 used to expand the tubular body 12 from the nonexpanded first position to the expanded second position. Thus, after the tubular body 12 is formed by the lathe, it is in the second expanded position. Laser etching of the tubular body 12 may be performed, for example, by the Inter-Therapeutics Co. of Minneapolis, Minnesota. Alternatively, the stent 10 may also be manufactured by chemical etching wherein the tubular body 12 is coated with a material resistant to chemical etching. The tubular body 12 is then etched to remove the desired material to obtain the desired structure. Advantageously, the etching process develops smooth openings in the tubing wall without burrs or other artifacts that are characteristic of conventional mechanical or laser machining processes. One skilled in the art will appreciate that the stent 10 can be manufactured by other known methods.

The stent 10 is preferably manufactured according to known techniques so that the shape memory metal reacts is a predetermined manner when the stent is reheated to a predetermined temperature. Specifically, the stent 10 is preferably manufactured such that it reacts in a predetermined manner when the metal is heated to approximately body temperature of about 96 F (35 C). The stent 10 may also be treated using known methods during the manufacturing process, such as heat treating, annealing, polishing, etching, cleaning, and the like. Additionally, the coating 80 is preferably applied to the outer portion of the tubular body 12. In particular, the tubular body 12 is dipped into liquid PTFE at a temperature of about 575 F (300 C) and then the tubular body is then cooled to about 0 C (-32 F) to soften or mollify the PTFE coating. Advantageously, the PTFE coating is durable and long lasting, as discussed in the instant assignees related U.S. Letters Patents, which have been expressly incorporated herein by reference.

After the coating 80 is applied, the stent 10 is compressed or deformed into the first position. The stent 10 may be deformed by attaching it to a fixture and reducing it in steps until the first nonexpanded position is reached. In a preferred

embodiment, the shape memory metal is cooled below a predetermined temperature and then the body 12 is deformed into the first nonexpanded position. The tubular body 12 is then kept below that predetermined temperature so that it will not self-expand to the expanded second position. Desirably, the predetermined temperature is about body temperature 96 F (35 C) so that the stent 10 self-expands when heated to body temperature. One skilled in the art will appreciate that various known methods may be used to construct the stent 10 and the stent may be formed in either the nonexpanded or extended positions.

In use of a preferred embodiment of the stent 10, as seen in Figure 8, the stent is attached proximate the distal end of a catheter system 90 in the first nonexpanded position and the stent is at a temperature below body temperature, such as about -32 F (0 C). A sheath 92 is attached to the catheter system 90 and it is used to protect and insulate the stent 10 from heat. The stent 10 is then placed into the desired position inside the body, such as a blood vessel 94, and the sheath 92 is removed as shown in Figure 9. The heat from the body warms the stent 10 and that causes the shape memory metal to self-expand into the second expanded position shown in Figure 10. The stent 10 is desirably configured to permanently stay in that expanded position while securely engaging the inside wall of the blood vessel 94. Advantageously, the stent 10 does not include any inwardly extending projections that interfere with the flow of fluids through the vessel 94. The stent 10, which is pressed into the wall of the vessel 94, will eventually be covered with endothelial or other natural material and that minimizes interference with the blood flowing through the vessel.

Alternatively, the stent 10 is deliverable to the desired location by mounting it on an expandable member 100 of a delivery catheter system 102. For example, as shown in Figure 11, the stent 10 is positioned over the expandable member 100, such as a balloon, of the catheter delivery system 102. The stent 10 is mounted to the catheter delivery system 102 in its nonexpanded state and it is inserted into the body lumen of the patient. The stent 10 may be attached to the expandable member by a variety of known ways such as compressing the stent onto the balloon, providing ridges or protrusions of the balloon to prevent longitudinal movement of the stent, using bio-compatible adhesives, etc. As shown in Figure 12, the balloon 100 is inflated to expand the stent 10 into the expanded second position and the stent engages the inner surface of the blood vessel 94.

In greater detail, the stent 10 is positioned about the inflatable balloon 100

located near the distal end 104 of the delivery catheter system 102. The balloon 100 is slightly inflated to secure the stent 10 to the exterior surface of the balloon. The catheter system 102 and stent 10 is then introduced into the patient's vascular system by any known technique. A guidewire 106 is disposed across the damaged arterial section and the catheter system 102 and stent 10 is advanced over the guidewire until it is positioned in the desired location. The balloon 100 is then expanded and this causes the stent 10 to expand against the artery wall 94. The engagement of the stent 10 with the artery wall 94 may be sufficient to hold the stent in the desired position. The stent 10, however, may also include one or more outwardly extending members (not shown) to securely engage the artery wall 94.

During use of the stent 10, the first section 24 and second section 60 are preferably configured such that as the tubular body 12 expands, a generally uniform radially outward force is applied against the inner wall of the lumen. Additionally, the stent 10 preferably expands in a generally circular configuration to maintain a generally uniform force on the inner wall of the lumen. Advantageously, the substantially uniform radially outwardly directed force minimizes stresses and deformation of the lumen. It will be understood, however, that the stent 10 may be constructed to expend asymmetrically or in any desired configuration. Further, generally the same outwardly directed radial force is applied along the entire longitudinal length of the stent 10. It will be appreciated, however, that various amounts of force may be applied to different sections of the lumen. For example, less outward force may be applied by the distal ends 18, 20 of the stent 10 and greater outward force may be applied by the center portion 22 of the stent. Fig. 14 through Fig. 18 likewise comprise a series of substantially non-foreshortening embodiments of the instant teachings which have been made in prototype form and coated with PTFE/ePTFE. Those having a modicum of skill will readily understand how the foregoing description applies to these teachings as each iteration of a stent 10, of the present invention addresses and solves the longstanding issues enumerated. Likewise, applicants' proprietary coating technology available from (Baxter Healthcare Corp., Laguna Hills, California) further comprising PTFE as discussed in U.S. Letters Patents No.'s 5,976,192 and 5,928,279, expressly incorporated herein by reference is understood by artisans to be useful for maintaining biocompatibility of any of the instant stents and the patency of body lumens indicated for treatment thereby. The teachings of the present invention have

known applications and usages within various body lumens and are in no way limited to peripheral vascular emplacement, although the illustrative examples, embodiments and iterations clearly have found substantial utility when used within systems indicated for treatment of such vessels.

Although this invention has been described in terms of certain preferred embodiments, the invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is Claimed:

1. A tissue supporting device, comprising:

an elongated body having a generally tubular configuration extending generally along a longitudinal axis, said body including a first nonexpanded position with a first diameter and a second expanded position with a second diameter, said second diameter being larger than said first diameter, said elongated body including at least one first section with one or more radially expandable elements and at least one second section with one or more flexible links, said radially expandable elements having a generally rectangular configuration in said first nonexpanded position and said radially expandable elements being sized and configured to expand radially to change the diameter of said elongated body from said first diameter to said second diameter, and said flexible links being sized and configured to straighten such that a longitudinal length of the elongated body is generally the same in said first position and in said second position.

2. The tissue supporting device of Claim 1, wherein said radially expandable elements are generally aligned with said longitudinal axis of said elongated body in said first position.

3. The tissue supporting device of Claim 1, wherein said radially expandable elements have generally diamond-shaped configuration in said second position.

4. The tissue supporting device of Claim 1, wherein each of said radially expandable elements include a first hinge point, a second hinge point, a first end and a second end.

5. The tissue supporting device of Claim 4, wherein said first hinge point, said second hinge point, said first end and said second end are interconnected by connecting members.

6. The tissue supporting device of Claim 1, further comprising one or more curved sections in each of said flexible links, said curved sections being adapted to straighten as said elongated body changes from said first positions to said second position.

7. The tissue supporting device of Claim 1, wherein said elongated body is constructed from a shape memory metal.

8. The tissue supporting device of Claim 7, wherein said shape memory metal is an alloy containing nitinol.

9. The tissue supporting device of Claim 1, wherein said elongated body expands from said first position to said second position when said body is heated to a predetermined temperature.

10. The tissue supporting device of Claim 9, wherein said predetermined temperature is approximately the temperature of the tissue to be supported.

11. The tissue supporting device of Claim 1, further comprising a coating covering at least a substantial portion of said elongated body.

12. An expandable stent including an elongated body extending generally along a longitudinal axis, said elongated body comprising:

a plurality of first sections including one or more radially expandable elements, each of said expandable elements including four hinge points interconnected by four connecting members; and

a plurality of flexible links interconnecting said plurality of first sections to from the elongated body;

wherein said flexible links include one or more curved sections that are configured to straighten as the expandable stent expands from a first position to a second position.

13. The expandable stent of Claim 12, wherein said plurality of flexible links includes a first pair of flexible links connected to each of said first sections and a second pair of flexible links connected to each of said first sections.

14. The expandable stent of Claim 13, wherein said links in said first pair of flexible links are mirror images of each other and wherein said links in said second pair of flexible links are mirror images of each other.

15. The expandable stent of Claim 12, further comprising a first position wherein the stent is deployable into the body and a second position wherein the stent is deployed inside the body.

16. The expandable stent of Claim 15, wherein said four connecting members are arranged in a generally parallel alignment in said first position and wherein said four connecting members form a substantially diamond-shaped configuration in said second position.

17. The expandable stent of Claim 15, wherein said radially expandable elements expand radially as said elongated body changes from said first position to said second position.

18. The expandable stent of Claim 15, wherein a longitudinal length of the elongated body is generally the same in said first position and in said second position.

19. An expandable stent having a longitudinal axis, said stent including a first nonexpanded position with a first diameter and a second expanded position with a second diameter, said expandable stent comprising:

a plurality of radially expandable elements, each of said radially expandable elements comprising:

a first connecting member being generally aligned with the longitudinal axis in said first position;

a second connecting member connected to said first connecting member, said second connecting member being generally aligned with the longitudinal axis in said first position;

a third connecting member connected to said second connecting member, said third connecting member being generally aligned with the longitudinal axis in said first position;

a fourth connecting member connected to said third connecting member, said fourth connecting member being generally aligned with the longitudinal axis in said first position; and

a plurality of flexible links interconnecting said plurality of radially expandable elements, each of said flexible links including a first end, a second end, and at least one curved sections.

20. The expandable stent of Claim 19, wherein said first, second, third and fourth connecting members are pivotally connected to form a generally rectangular shaped configuration in said first nonexpanded position.

21. The expandable stent of Claim 19, wherein said first, second, third and fourth connecting members are pivotally connected to form a generally diamond-shaped configuration in the second expanded position.

22. The expandable stent of Claim 19, wherein a first end of a flexible link from said plurality of flexible links is connected to a first group of radially expandable elements and a second end of said flexible link is connected to a second group of said radially expandable elements to interconnect said first and second groups of radially expandable elements.

23. The expandable stent of Claim 19, wherein two or more radially expandable elements from said plurality of radially expandable elements are connected to form a group and wherein two pairs for flexible links from said plurality of flexible links are connected to said group.

24. An expandable stent including a generally tubular body extending along a longitudinal axis, said expandable stent including a first nonexpanded position and a second expanded position, said expandable stent comprising:

a plurality of first section, each of said first sections including one or more radially expandable elements, each of said radially expandable elements including a first end, a second end, a first hinge point positioned between said first end and said second end, and a second hinge point positioned between said first end and said second end;

a plurality of second sections interconnecting said plurality of first sections, said second sections including one or more flexible links having a first end, a second end, and at lest one curved section; and

wherein said flexible links are connected to said first hinge point or said second hinge point of said radially expandable members.

25. The expandable stent of Claim 24, wherein said plurality of first sections are radially spaced apart about a circumference of the generally tubular body.

26. The expandable stent of Claim 24, wherein said curved sections of said flexible links are straightened as the stent expands from the first nonexpanded position to the second expanded position.

27. The expandable stent of Claim 24, wherein said stent has substantially the same overall longitudinal length in said first nonexpanded position and said second expanded position.

28. An expandable stent having a generally tubular configuration and extending generally along a longitudinal axis, said stent comprising:

a plurality of first sections, each first section including a plurality of radially expandable elements having a first end, a second end, a first hinge point and a second hinge point; each of said radially expandable elements including a first connecting member connecting said first end and said first hinge point, a second connecting member connecting said first hinge point and said second end, a third connecting member connecting said second end and said second hinge point, and a forth connecting member connecting said second hinge point and said first end; and

a plurality of second sections interconnecting said first sections, each of said second sections including a plurality of flexible links and each of said flexible links includes at least one curved section.

29. The expandable stent of Claim 28, wherein each of said plurality of radially expandable elements are sized and configured to expand into a generally diamond-shaped configuration.

30. The expandable stent of Claim 28, wherein said flexible members are adapted to lengthen upon the expansion of the expandable stent to compensate for the tendency of the expandable stent to foreshorten when the stent is expanded.

31. The expandable stent of Claim 28, wherein the expandable stent has generally the same overall length as the stent expands.

32. A stent for expanding a lumen in a body, the stent comprising:

one or more first portions including a plurality of radially expandable elements, each of said radially expandable elements including a plurality of connecting members that are connected at a plurality of hinge points, each of

said radially expandable elements being sized and adapted to expand into a generally diamond-shaped configuration; and

one or more second portions connected to said first portions, each of said second portions including a pair of flexible links, each of said flexible links having a first end with a first curved section, a second end with a second curved section and a center portion with a third curved portion.

33. The stent of Claim 32, wherein said first curved section and said second curved portion are curved at an angle greater then 90.

34. The stent of Claim 32, wherein each flexible link from said pairs of flexible links are mirror images of each other.

35. An endovascular or biliary stent comprising:

a plurality of linked supporting members defining a tubular supporting means having an inner and outer surface for maintaining patency of a body lumen, wherein emplacement at one position and expansion to a second position maintains a substantially non-foreshortened means for supporting the subject body lumen.

36. The stent as defined by Claim 35, having at least a coating of ePTFE on at least one of the inner and outer surfaces.

37. The stent as defined by Claim 35, wherein said plurality of linked supporting members defines at least two distinct geometrical arrangements.

38. The stent as defined in Claim 35, whereby a substantially identical geometry of the linked supporting members of said both first and second positions is defined.

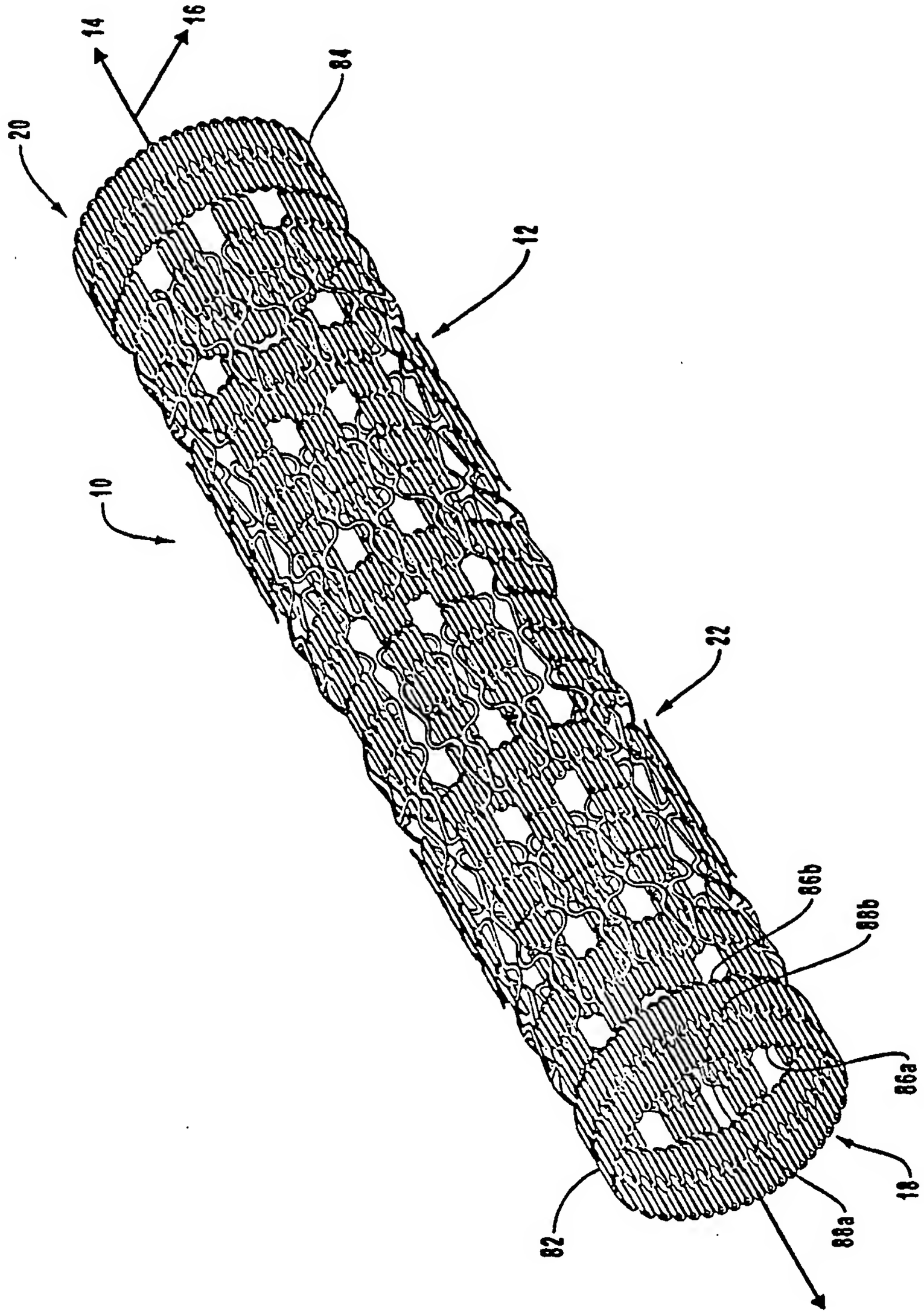

FIG. 1

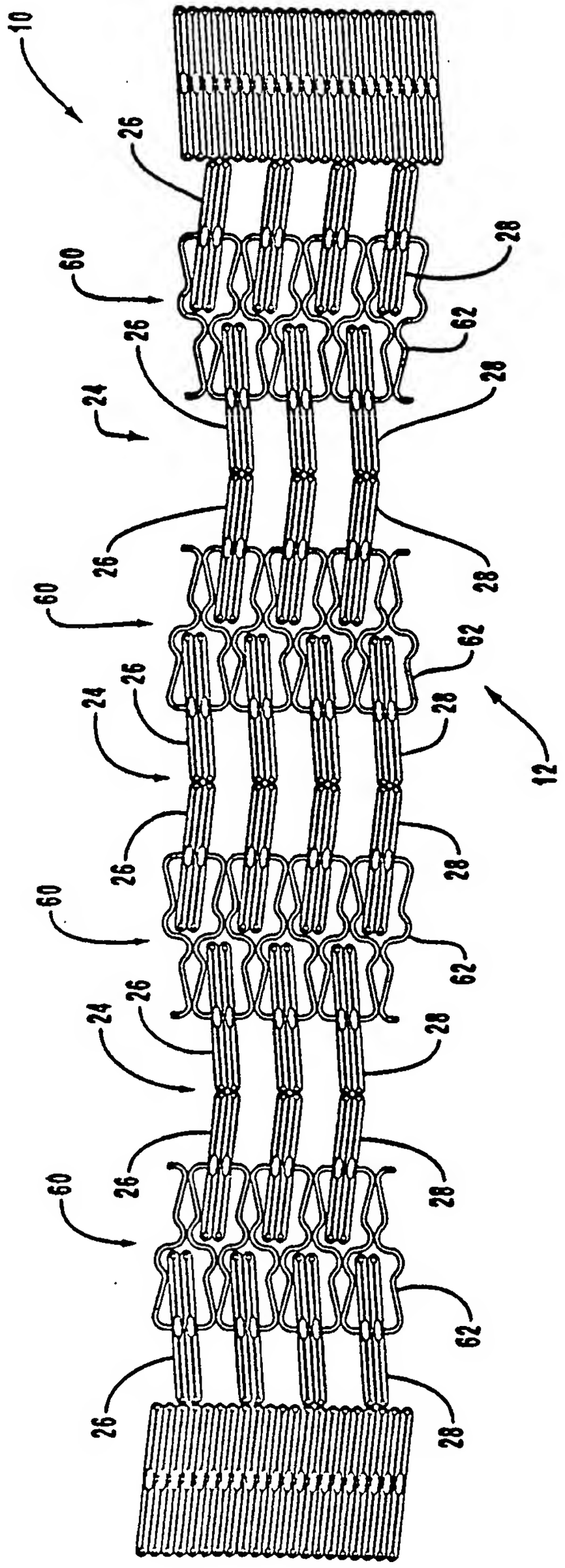

FIG. 2

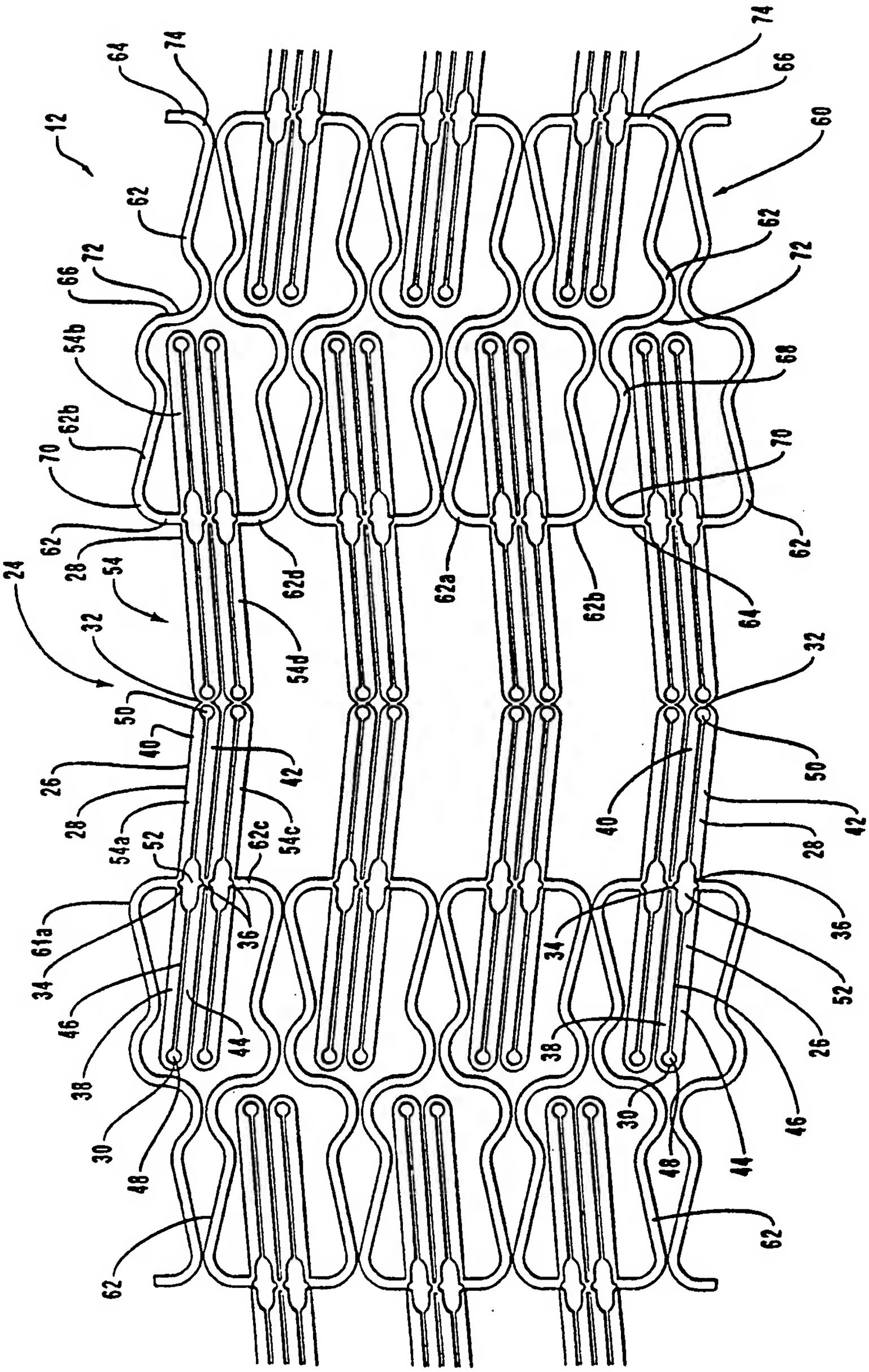
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FIG. 3

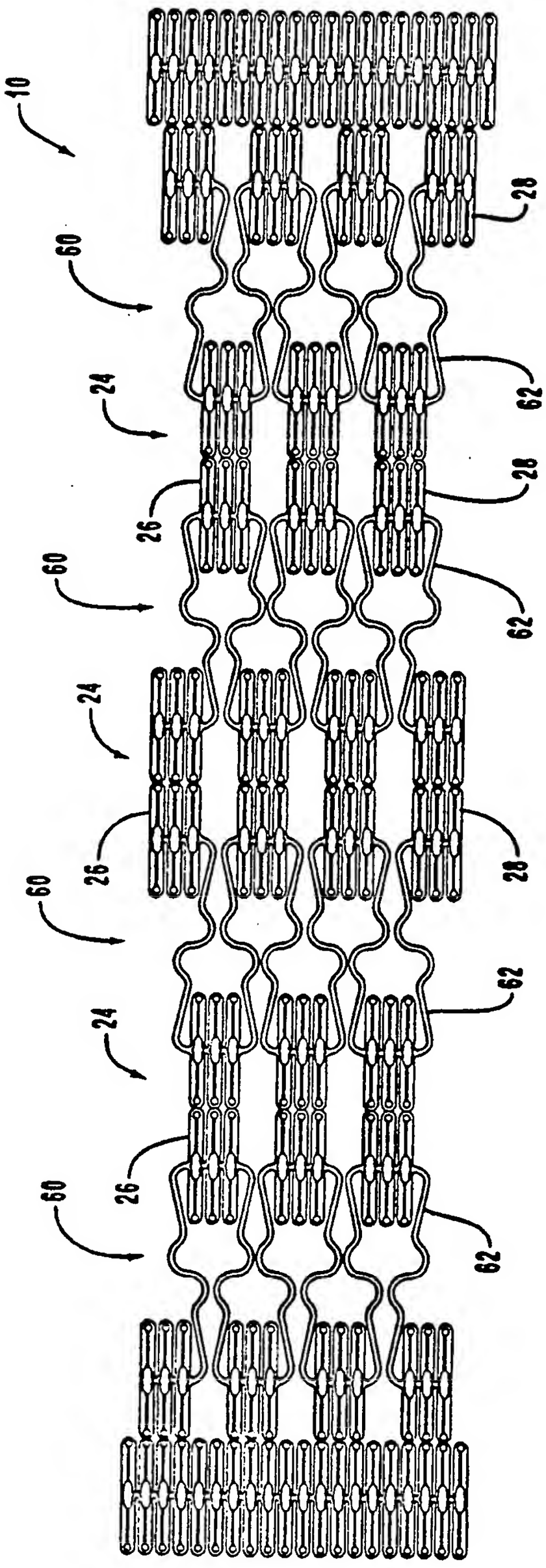

FIG. 4

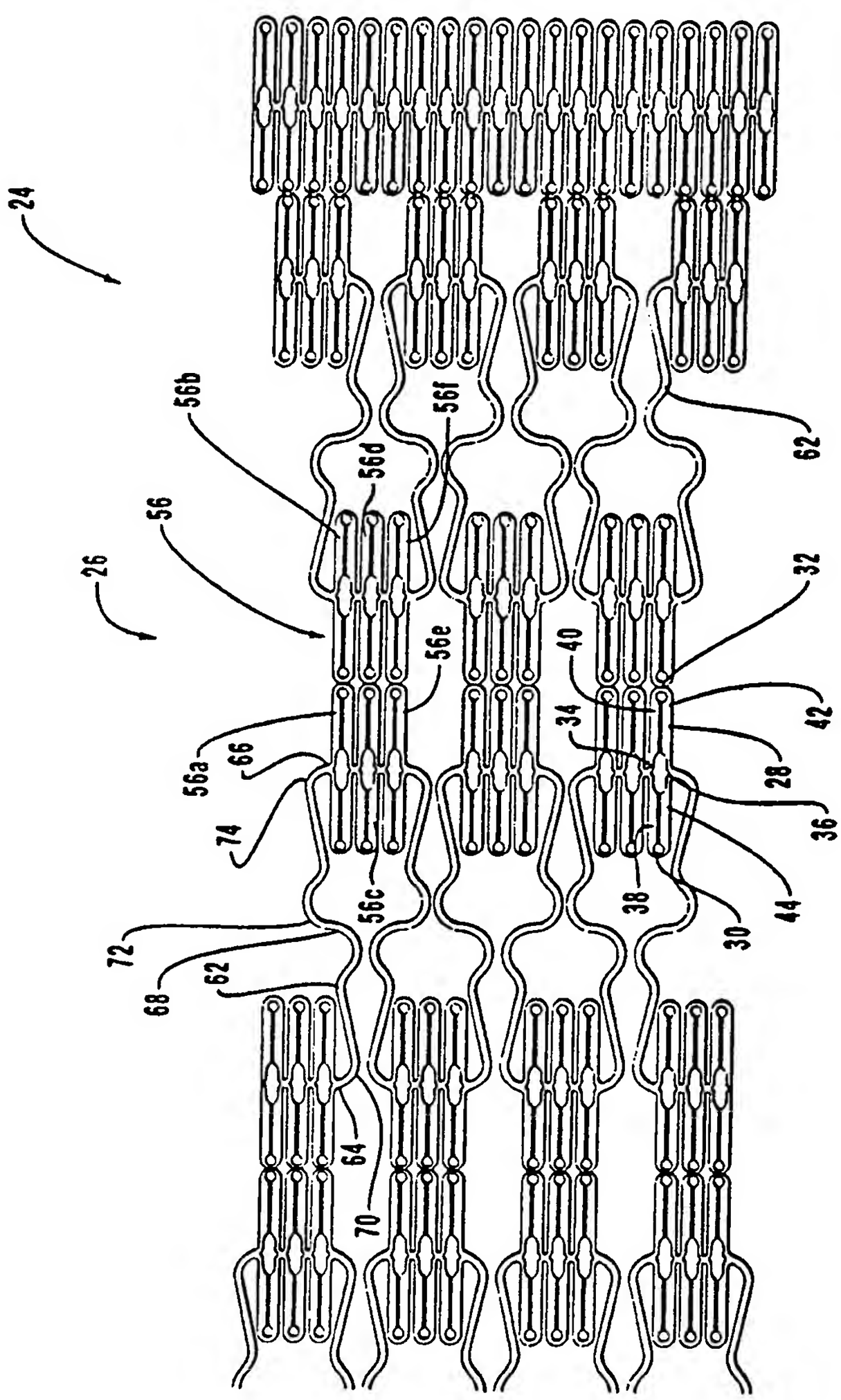
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FIG. 5

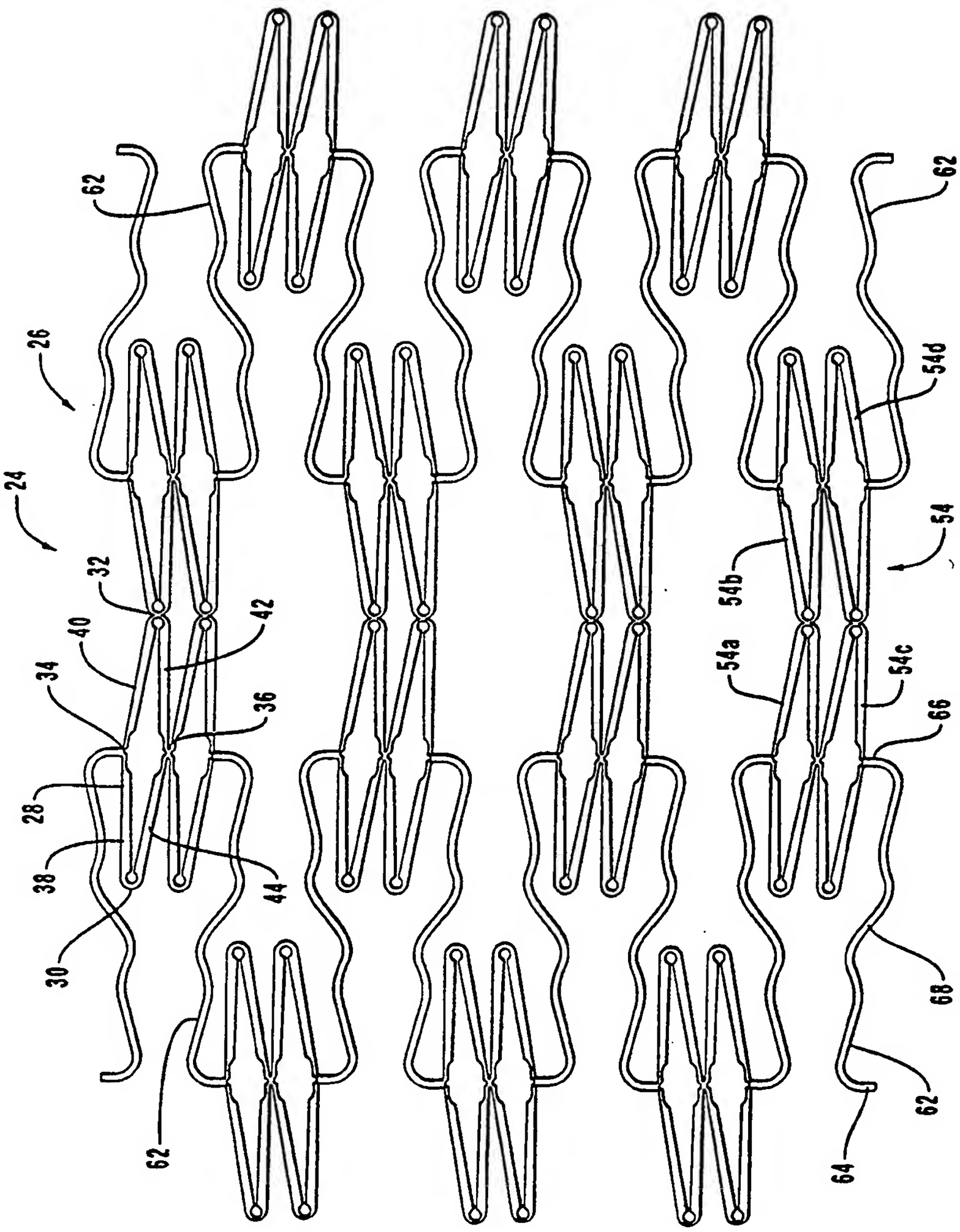

FIG. 6

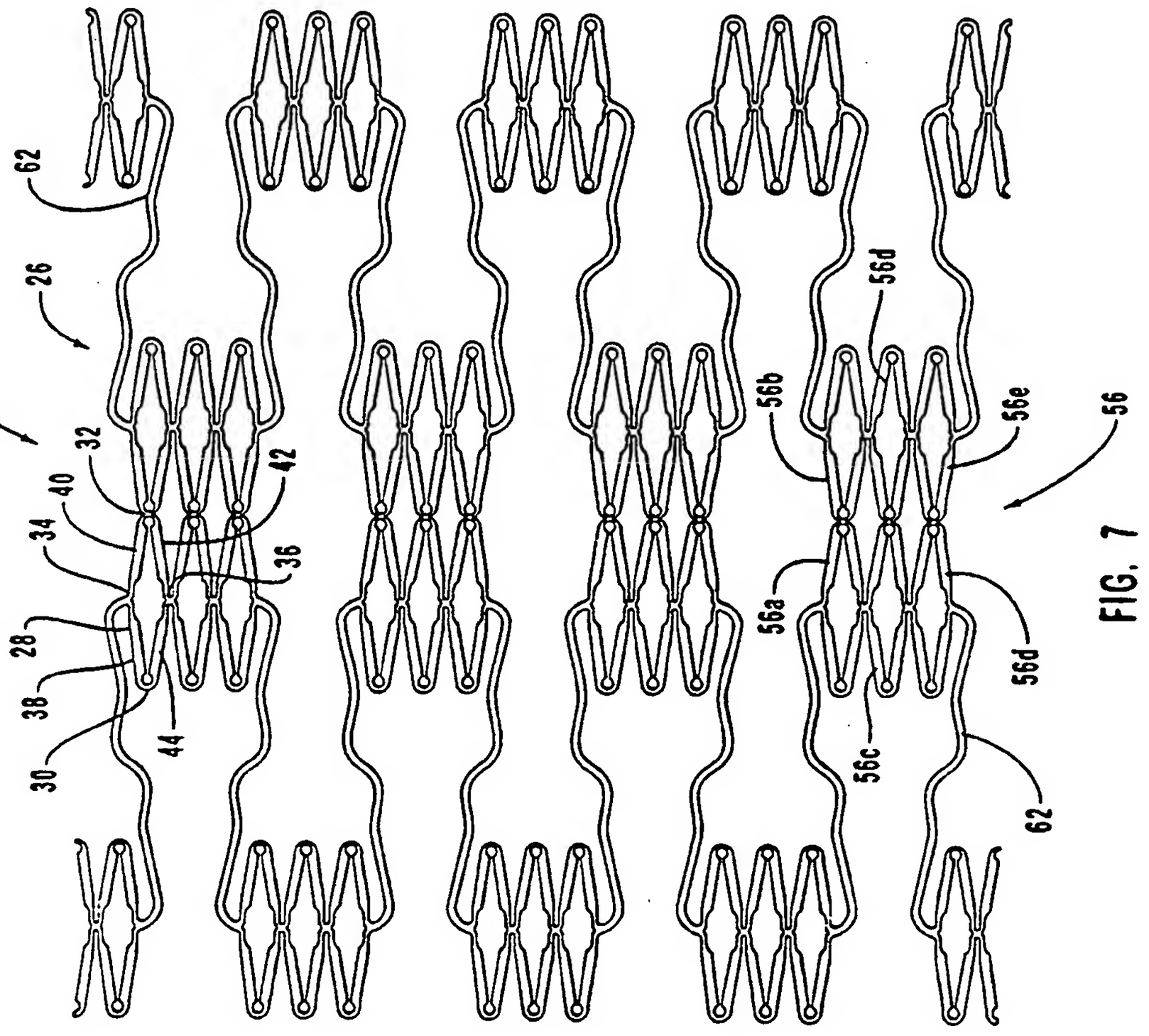

FIG. 7

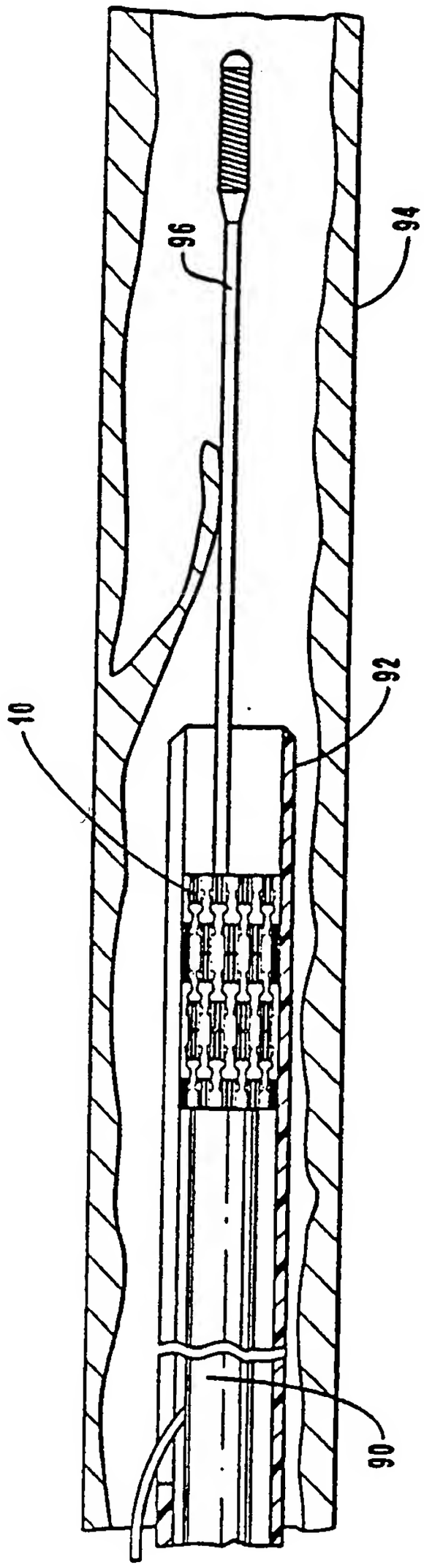

FIG. 8

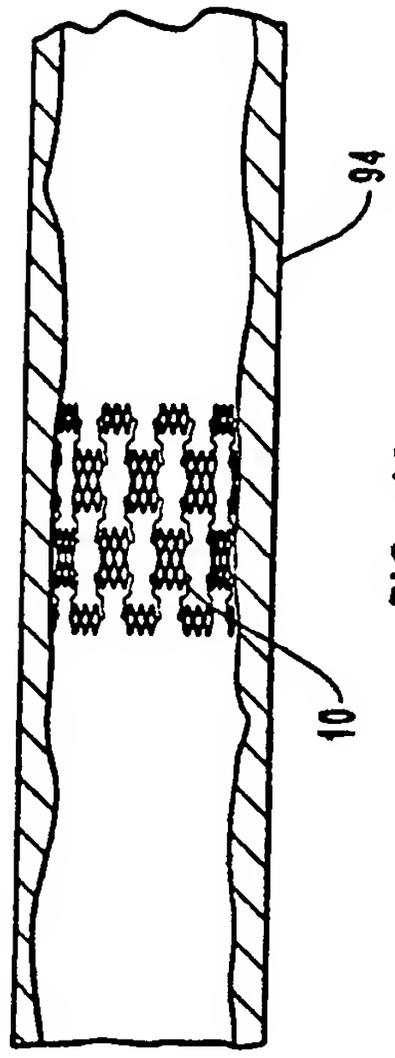

FIG. 10

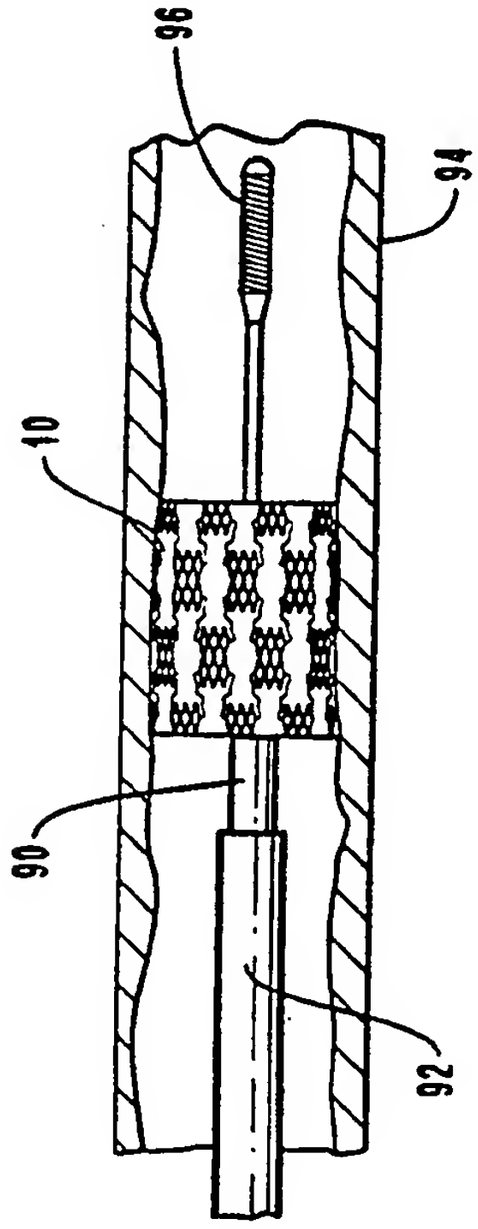

FIG. 9

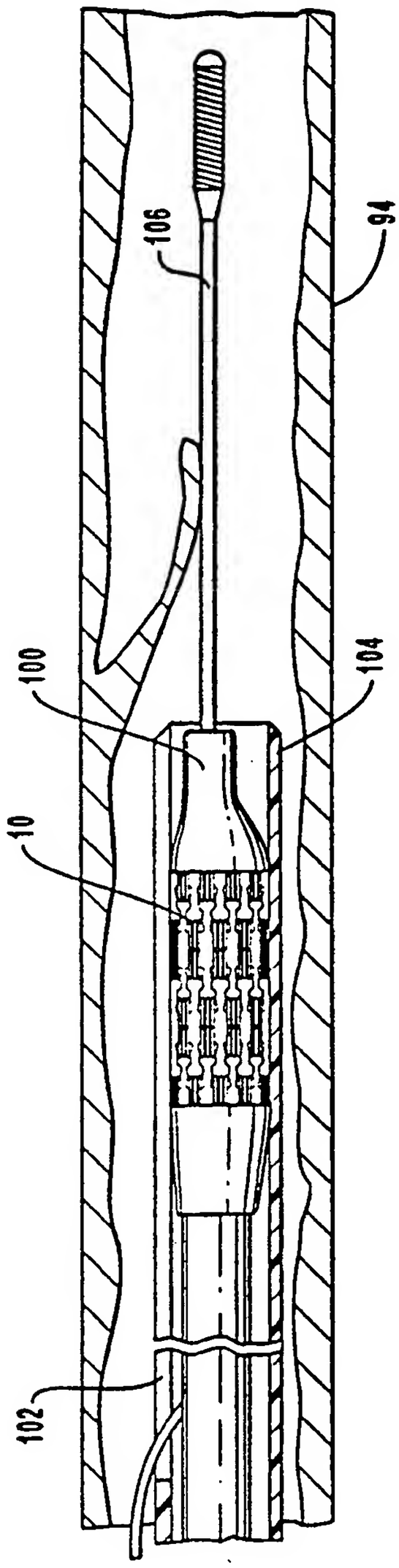

FIG. 11

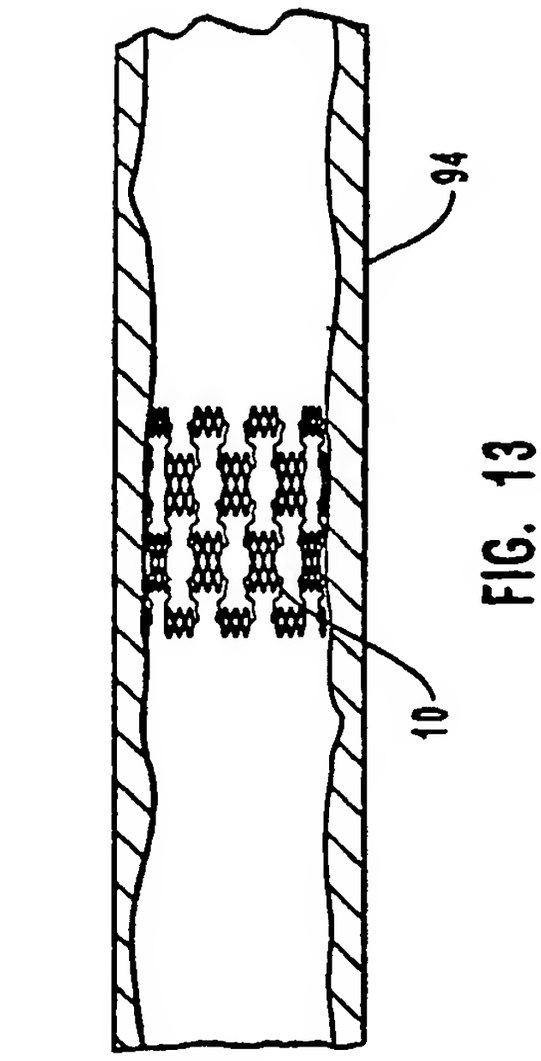

FIG. 13

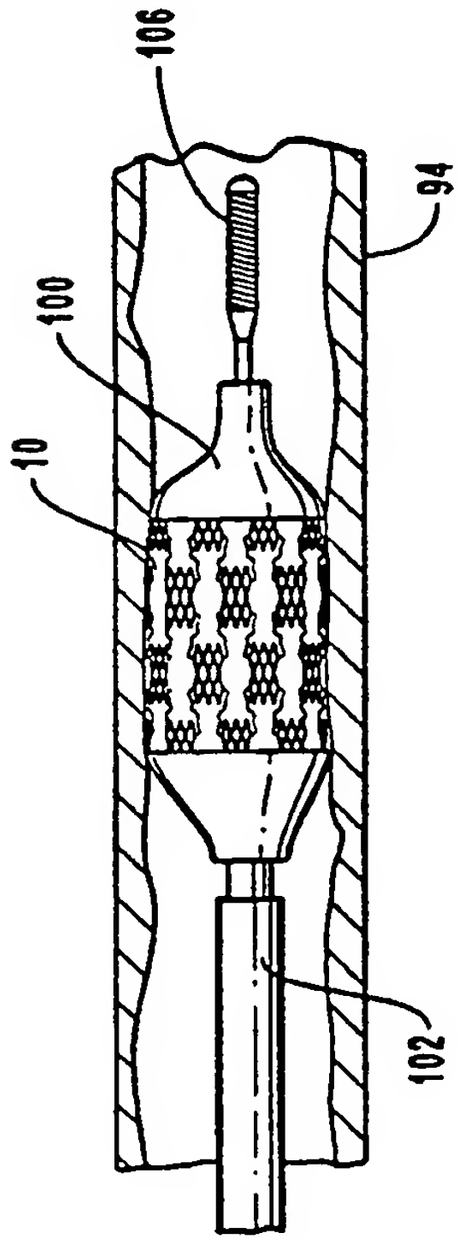

FIG. 12

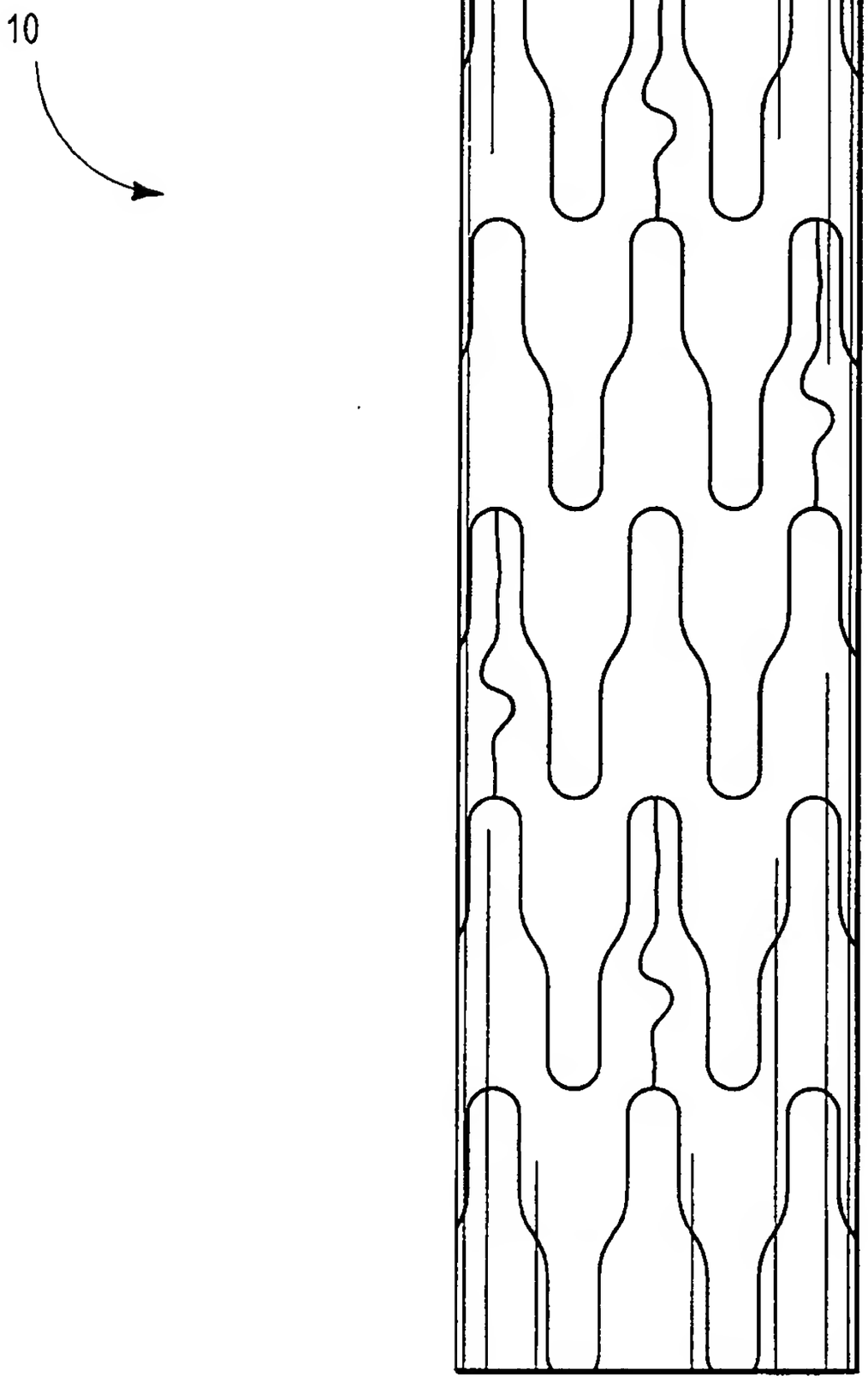

FIG. 14

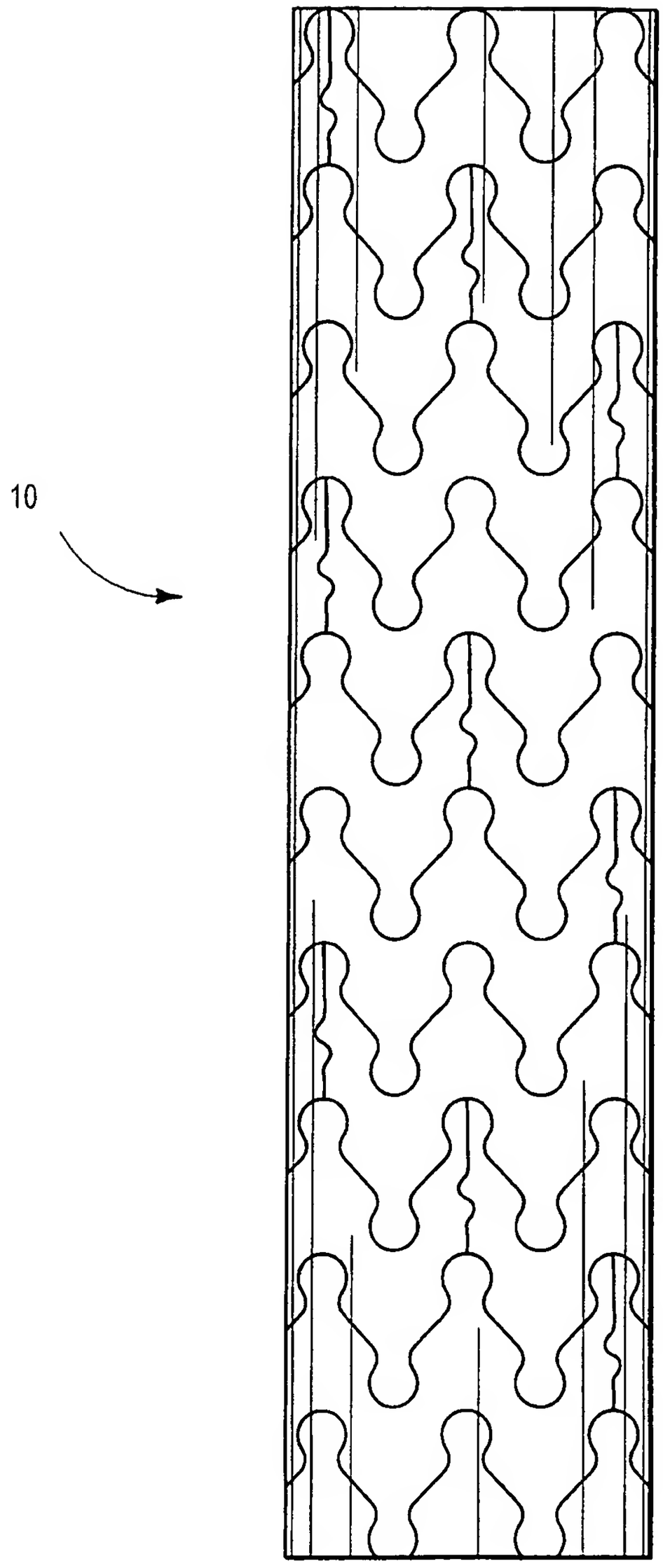

FIG. 15

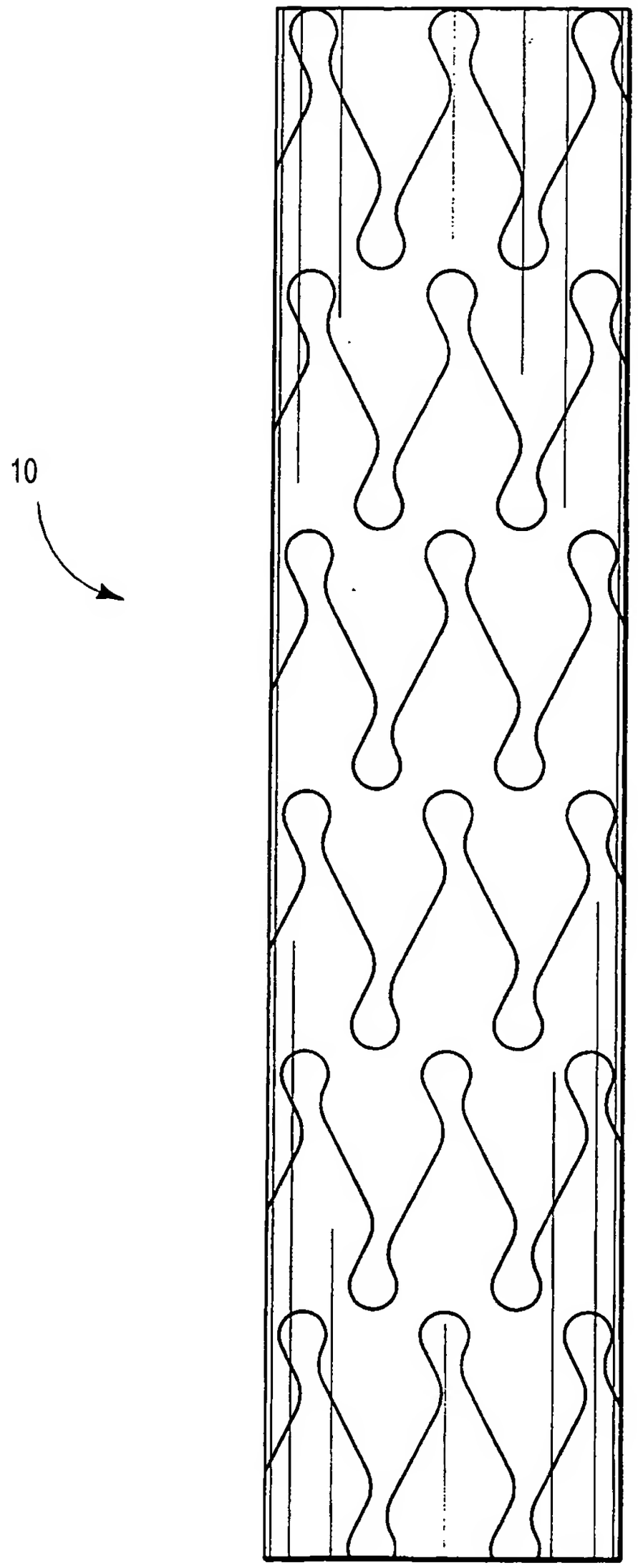

FIG. 16

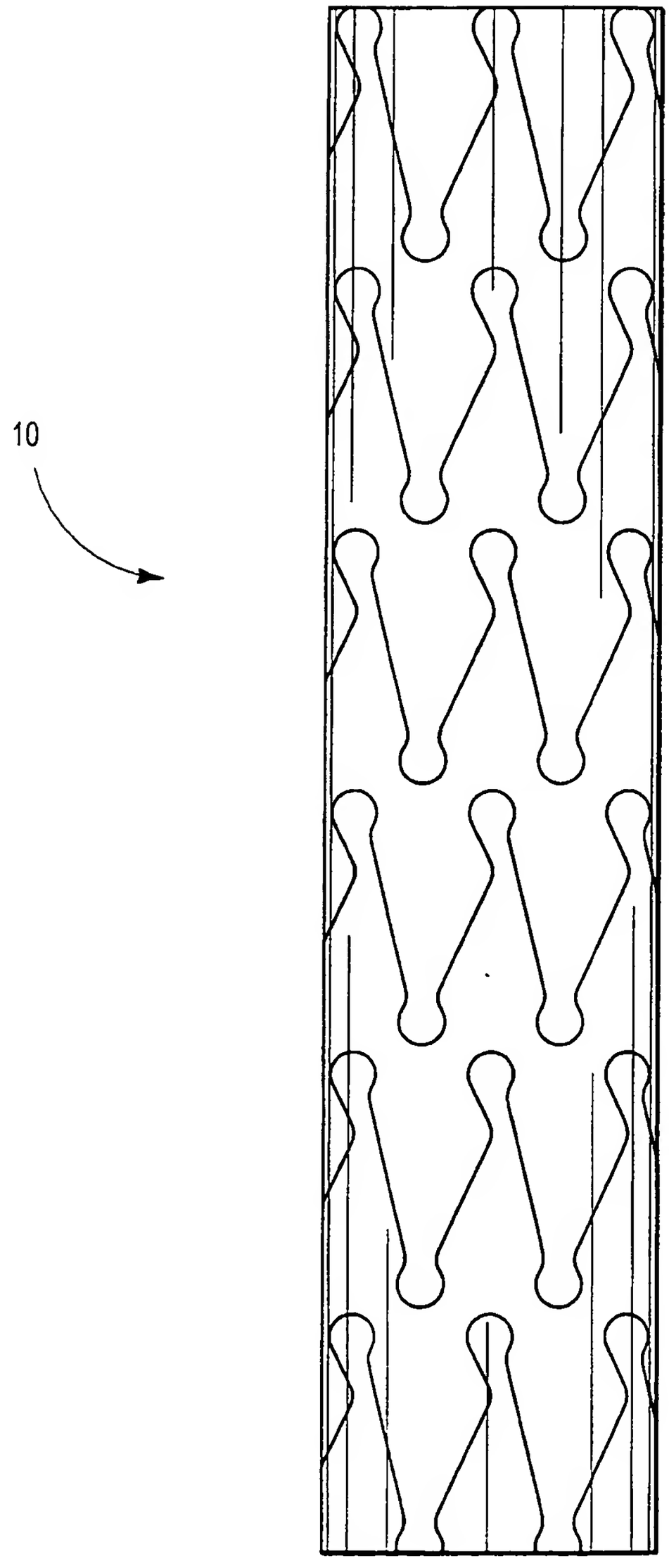

FIG. 17

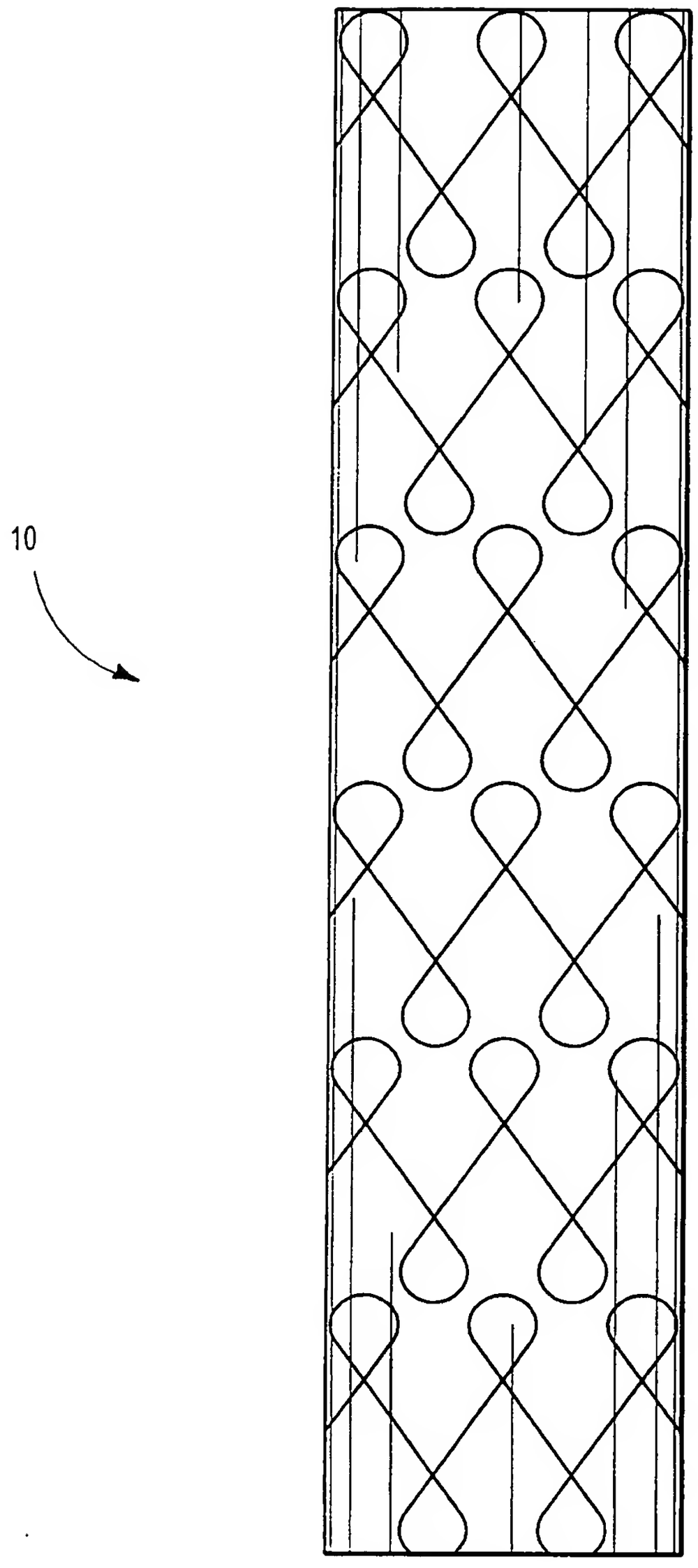

FIG. 18

INTERNATIONAL SEARCH REPORT

Inter onal Application No
PCT/US 00/33250

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 18888 A (SCIMED LIFE SYSTEMS INC) 22 April 1999 (1999-04-22) figures 1A-7D page 4, line 5 - line 16 page 4, line 21 - line 27 page 8, line 35 -page 10, line 14 claims 1-14	1,2,4-6, 11-15, 17-20, 22-28, 30,31, 35,37,38
A	---	32

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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'&' document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 April 2001	26/04/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

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INTERNATIONAL SEARCH REPORT

Inter onal Application No
PCT/US 00/33250

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 12495 A (ALTER ROBERT ;STARCK BERND (DE); MICRO SCIENCE MEDICAL AG (DE)) 18 March 1999 (1999-03-18) figures 1,2 page 4, line 30 -page 6, line 13	1,3,12, 15,16, 19,21, 24,28,35
A	---	32
P,X	US 6 083 259 A (FRANTZEN JOHN J) 4 July 2000 (2000-07-04) figures 1-3 column 4, line 59 -column 5, line 46 column 6, line 3 - line 19	1,2, 4-10,12, 19, 24-28, 30,31, 35,37,38
A	---	32
A	WO 99 49811 A (QUANAM MEDICAL CORP) 7 October 1999 (1999-10-07) figure 1 page 3, line 6 -page 4, line 22	1-38

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/33250

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		AU 3116499 A	18-10-1999
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